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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,044	03/08/2005	Brian Thomas Campbell	MS0010P	7005
210	7590	10/28/2005	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			FREISTEIN, ANDREW B	
			ART UNIT	PAPER NUMBER
			1626	
DATE MAILED: 10/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/527,044

Applicant(s)

CAMPBELL ET AL.

Examiner

Andrew B. Freistein

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### ***DETAILED ACTION***

Claims 1-28 are currently pending in the instant application.

### ***Priority***

This application is a 371 of PCT/US03/28344, filed 09/09/2003, which claims benefit of US Provisional Application No. 60/410,549, filed 09/13/2002.

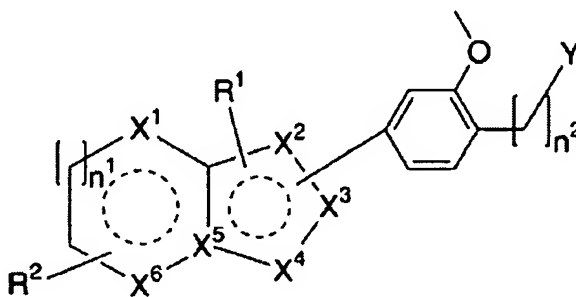
### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a general inventive concept under PCT Rule 13.1.

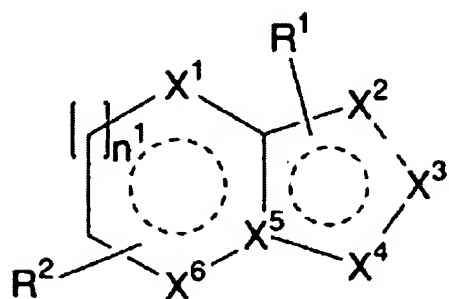
Due to the numerous and widely-divergent variables in the compound of Formula (I), (e.g.  $X^1$ ,  $X^2$ ,  $X^3$ ,  $X^4$ ,  $X^5$ ,  $X^6$ ,  $R^1$ ,  $R^2$ , Y,  $n^1$  and  $n^2$ ), a precise listing of all inventive groups cannot be made. **The following groups are exemplary:**

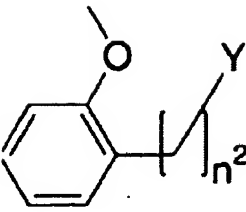
**Group I: Claims 1-28 (in part),** drawn to compounds and pharmaceutical

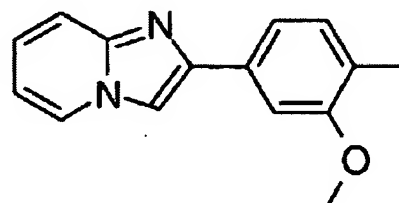


compositions of Formula I, , methods of treatment thereof, wherein  $X^1$ ,  $X^2$ ,  $X^4$ , and  $X^6$  are C or N;  $X^3$  is C;  $X^5$  is N; Y is pyridyl;  $R^1$  is halogen or  $C_{0-4}$ alkyl; and  $R^2$  is halogen or  $C_{0-4}$ alkyl;  $n^1$  is 1;  $n^2$  is 0; and

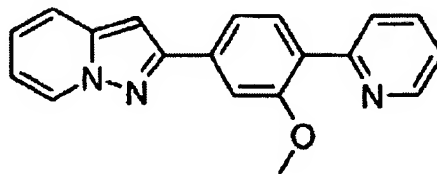
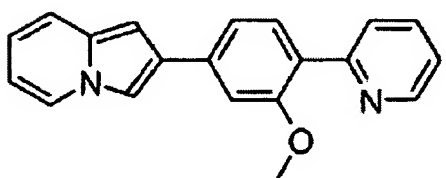
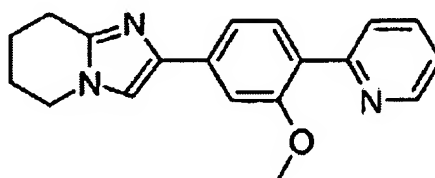
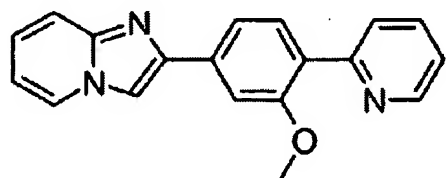
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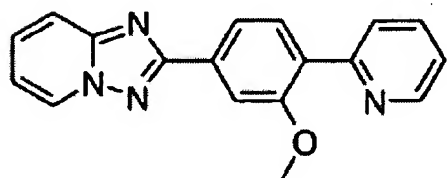
bonds to  at the X<sup>3</sup> position.



Examples of compounds found within this group are:

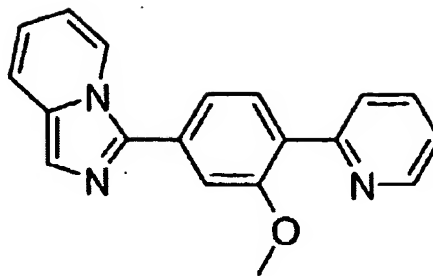


, and

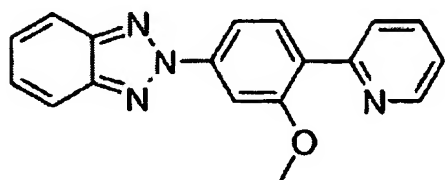


**Group II: Claims 1-28 (in part),** drawn to compounds and pharmaceutical compositions of Formula I and methods of treating thereof, wherein X<sup>1</sup>, X<sup>2</sup>, X<sup>3</sup>, X<sup>4</sup>, and X<sup>6</sup> are C or N; X<sup>5</sup> is C; Y is pyridyl; R<sup>1</sup> is halogen or C<sub>0-4</sub>alkyl; and R<sup>2</sup> is halogen or C<sub>0-</sub>

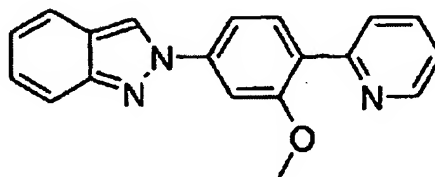
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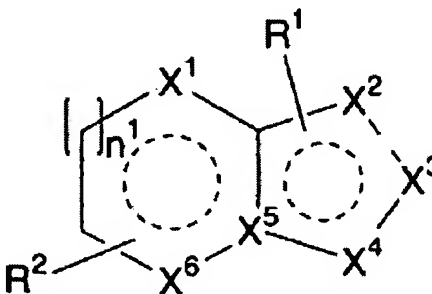
alkyl;  $n^1$  is 1; and  $n^2$  is 0. Examples are:



, and

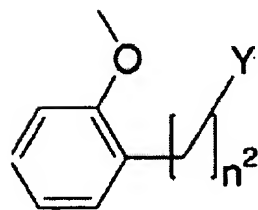


**Group III: Claims 1-28 (in part)**, drawn to compounds and pharmaceutical compositions of Formula I and methods of treating thereof, wherein  $X^1$  is S or O;  $X^2$  is N or C;  $X^3$ ,  $X^4$  and  $X^6$  are C;  $X^5$  is N; Y is pyridyl;  $R^1$  is halogen or  $C_{0-4}$ alkyl; and  $R^2$  is

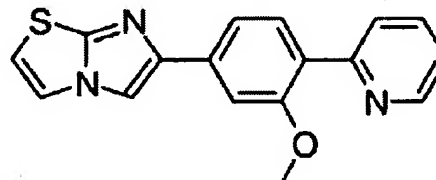


halogen or  $C_{0-4}$ alkyl;  $n^1$  is 0;  $n^2$  is 0; and

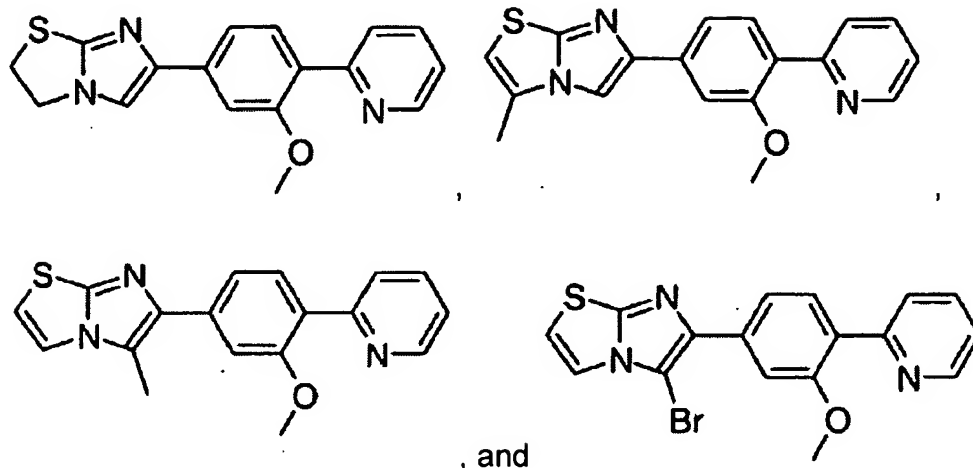
bonds to



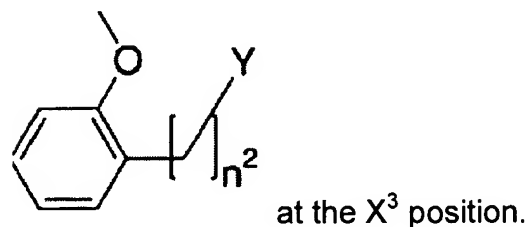
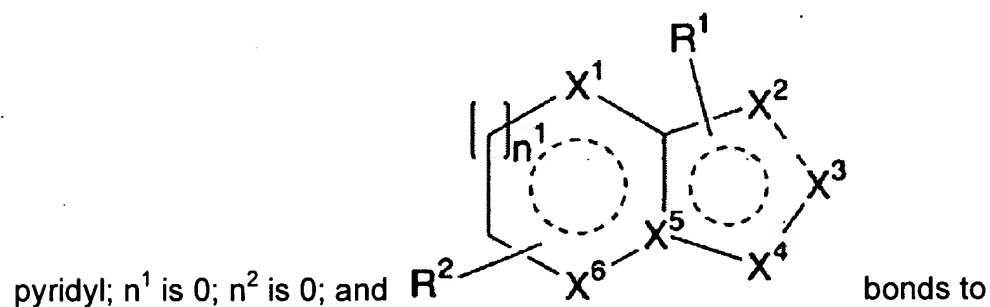
at the  $X^3$  position. Examples are:



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**Group IV: Claims 1-28 (in part)**, drawn to compounds and pharmaceutical compositions of Formula I and methods of treating thereof, wherein  $X^1$  is S or O;  $X^2$  is N or C;  $X^3$ ,  $X^4$  and  $X^6$  are C;  $X^5$  is N; Y is pyridyl;  $R^1$  is halogen or  $C_{0-4}$ alkyl; and  $R^2$  is



**Group V: Claims 1-28 (in part)**, drawn to compounds and pharmaceutical compositions of Formula I and a method of treatment thereof, wherein variables  $X^1$ ,  $X^2$ ,  $X^3$ ,  $X^4$ ,  $X^5$ ,  $X^6$ ,  $R^1$ ,  $R^2$ , Y,  $n^1$  and  $n^2$  represent chemical groups and methods of treating

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not otherwise encompassed by the inventions of Groups I-IV above. If this group is elected, it may be subject to further restriction.

In accordance with 37 CFR § 1.499, **applicant is required, in reply to this action, to elect a single invention** to which the claims must be restricted. As stated above, this is not an exhaustive list, as it would be impossible under the time constraints due to the large volume of subject matter claimed in the instant application. Therefore, applicant may choose to elect a different invention (a product and a method of use of the product) by identifying another specific embodiment; i.e. to choose another value for  $X^1$ ,  $X^2$ ,  $X^3$ ,  $X^4$ ,  $X^5$ ,  $X^6$ ,  $R^1$ ,  $R^2$ ,  $Y$ ,  $n^1$  and  $n^2$  (where applicable) not listed in the exemplary groups of the invention above, and the examiner will endeavor to group that selection.

**In addition to an election of one of the above groups, restriction is further required under 35 U.S.C. 121 as follows:**

An election of one method of use is required: for example,

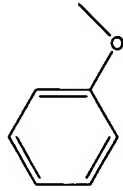
- A. Method of treating pain,
- B. Method of treating anxiety,
- C. Method of treating memory loss,
- D. Method of treating Alzheimer's disease,
- E. Method of treating dementia,
- F. Method of treating cognitive impairment,
- G. Method of treating Huntington's disease,
- H. Method of treating Parkinson's disease,
- I. Method of treating depression,

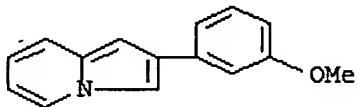
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J. Method of treating schizophrenia,

K. Method of treating drug addiction.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 because, pursuant to 37 C.F.R. § 1.475(a), the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution

over the prior art. The technical feature in the instant application is: , which does not define a contribution over the prior art, as can be demonstrated by Lins, Claudio L, "Nitro- para- and meta-substituted 2-phenylindolizines as potential antimicrobial agents," Journal of Pharmaceutical Sciences 71(5), pp. 556-61 (1982),

disclosing the compound , which contains the same technical feature claimed in the instant application. As a result, the technical feature of the instant application cannot be said to be a "special" technical feature. Therefore, unity of invention is lacking and restriction among the inventions identified is proper.

Moreover, the variables of Formula I vary extensively and, when taken as a whole, result in vastly different compounds, which would impose a serious burden on the examination of the application.

Further, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of



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invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

**As a result, the claims lack unity of invention and applicant is required to elect a single invention.**

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

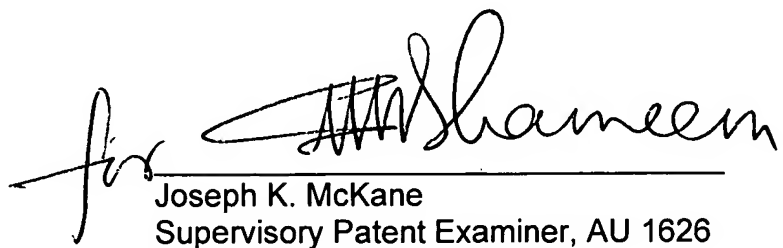
***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew B. Freistein  
Patent Examiner, AU 1626

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner, AU 1626  
Date: October 24, 2005